K010228

FEB 21 2001

Attachment IV
Special 510(k) Premarket Notification
GORE-TEX® DualMesh® PLUS Biomaterial with Holes

Premarket Notification 510(k) Summary

A. Submitter

W.L. Gore and Associates, Inc.
3750 W. Kiltie Lane
P.O. Box 900
Flagstaff, AZ 86002-0900

Contact: R. Larry Pratt

Date Submitted: January 23, 2001

B. Applicant Device

Trade Name: GORE-TEX® DualMesh® PLUS Biomaterial with Holes.

Classification Name: Surgical Mesh.

C. Applicant Device Description

Biocompatible, expanded polytetrafluoroethylene (ePTFE) loaded with antimicrobial preservative agents chlorhexidine diacetate and silver carbonate. Macropores are placed in the device. The device has one open microstructure surface and one closed microstructure surface. The open microstructure surface is textured with a "ridges and valleys" pattern to aid in surface identification and proper surface orientation.

D. Applicant Device Indications For Use

GORE-TEX® DualMesh® PLUS Biomaterial with Holes is indicated for use in the reconstruction of hernias and soft tissue deficiencies and for the temporary bridging of fascial defects. The antimicrobial preservative agents act as preservatives, thereby inhibiting bacterial colonization of the device for up to ten days post-implantation.

E. Predicate Device

The previously cleared GORE-TEX® DualMesh® PLUS Biomaterial with Holes with a "hexagon" identification pattern is cited as the predicate device.

F. Technological Characteristics

This Premarket Notification submission is for a modification to an existing, currently marketed device. The modification is to change the texturing pattern on the tissue ingrowth surface of the predicate device.

These changes do not change the device's intended use or indications. Similarly, the materials, design, biocompatibility, packaging and sterilization process for the applicant device have not changed from those for the predicate device.

Bench test data reveal the applicant device has mechanical strength and material characterization values which are substantially equivalent to the predicate device.

In-vitro antimicrobial activity test data demonstrate that the applicant device functions both safely and effectively to inhibit bacterial colonization of the device for up to ten days post-implantation. *In*-vivo animal test data document that the tissue response for the applicant device is equivalent to histological controls for the predicate device.

Design control and verification testing have been performed for this device modification.

G. Safety and Effectiveness Conclusions

This Premarket Notification concerns a modification to the surface identification pattern for use in proper surface orientation. The applicant device is substantially equivalent to the predicate device with regard to intended use, indications, possible complications, materials, design, biocompatibility, packaging, sterilization process, mechanical strength and material characterization values. *In-vivo* animal testing and *in-vitro* antimicrobial testing demonstrate the applicant device performs equivalent to the predicate device.

The modification described in this Premarket Notification does not raise questions of safety or effectiveness that have not been previously addressed. Both the applicant device and the predicate device perform their equivalent clinical functions by incorporating biocompatible materials to permanently or transiently bridge or support a tissue defect. The antimicrobial agents loaded on both the applicant device and the predicate device perform an equivalent preservative function by inhibiting bacterial colonization for up to ten days post-implantation.

The applicant device is substantially equivalent to the previously cleared predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 21 2001

Mr. R. Larry Pratt
Regulatory Affairs
W. L. Gore & Associates, Inc.
Medical Products Division
3750 West Kiltie Lane
Flagstaff, Arizona 86002

Re: K010228
Trade Name: GORE-TEX® DualMesh® PLUS Biomaterial with Holes
Regulatory Class: II
Product Code: FTL
Dated: January 23, 2001
Received: January 24, 2001

Dear Mr. Pratt:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K010228

Device Name: GORE-TEX® DualMesh® Biomaterial with Holes

Indications For Use:

For the reconstruction of hernias and soft tissue deficiences and for the temporary bridging of fascial defects.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Miriam C. Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010228

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Optional Format 1-2-96)